

HOUSE BILL 289

C8
HB 1159/09 – HGO & ECM

2lr1527
CF 2lr0662

By: **Delegate Feldman**

Introduced and read first time: January 27, 2012

Assigned to: Health and Government Operations and Economic Matters

A BILL ENTITLED

1 AN ACT concerning

2 **Economic Development – Maryland Stem Cell Research Act – Revisions**

3 FOR the purpose of altering the name of the Stem Cell Research Commission to be the
4 Stem Cell and Biotechnologies Commercialization Commission; requiring the
5 Commission to establish certain procedures and guidelines regarding research
6 supporting a qualified technology; repealing the requirement that the
7 Commission ensure that certain procedures and guidelines are based on certain
8 guidelines; altering the name of the Maryland Stem Cell Research Fund to be
9 the Maryland Stem Cell and Biotechnologies Commercialization Fund; altering
10 the purpose of the Fund; altering the approved uses of money in the Fund;
11 requiring that a certain percentage of awards per year be made to certain
12 for-profit companies; requiring that priority be given to certain applicants when
13 awarding funds to applicants in the nonprofit sector; altering the membership of
14 the Commission; altering the composition of the membership of the peer review
15 committee; requiring the peer review committee to consider certain factors
16 when reviewing a proposal; repealing the provision of law prohibiting a member
17 of the peer review committee from residing in the State; altering the
18 requirements for a certain report; altering the definition of certain terms;
19 defining a certain term; and generally relating to the Maryland Stem Cell
20 Research Act.

21 BY repealing and reenacting, with amendments,
22 Article – Economic Development
23 Section 10–429, 10–431, 10–432, 10–434 through 10–436, and 10–442
24 Annotated Code of Maryland
25 (2008 Volume and 2011 Supplement)

26 BY repealing and reenacting, without amendments,
27 Article – Economic Development
28 Section 10–430 and 10–437 through 10–441
29 Annotated Code of Maryland

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 (2008 Volume and 2011 Supplement)

2 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF
3 MARYLAND, That the Laws of Maryland read as follows:

4 **Article – Economic Development**

5 10–429.

6 (a) In this part the following words have the meanings indicated.

7 (b) “Adult stem cell” means a stem cell that is:

8 (1) derived from human tissue; and

9 (2) obtained after birth.

10 (c) “Commission” means the Stem Cell AND BIOTECHNOLOGIES
11 [Research] COMMERCIALIZATION Commission.

12 (d) “Committee” means the independent scientific peer review committee
13 that contracts with the Commission under § 10–436 of this subtitle.

14 (e) “Fund” means the Maryland Stem Cell AND BIOTECHNOLOGIES
15 [Research] COMMERCIALIZATION Fund established under § 10–434 of this subtitle.

16 (f) “Human cloning” means the replication of a human being through the
17 production of a precise genetic copy of nuclear human DNA or any other human
18 molecule, cell, or tissue in order to create a new human being or to allow development
19 beyond an embryo.

20 (g) “Institutional review board” has the meaning stated in the federal
21 regulations on the protection of human subjects.

22 (h) “Oocyte” means a female germ cell or egg.

23 (i) (1) **“QUALIFIED TECHNOLOGY” MEANS ANY INNOVATIVE AND**
24 **PROPRIETARY TECHNOLOGY THAT COMPRISES, INTERACTS WITH, OR ANALYZES**
25 **BIOLOGICAL MATERIAL, INCLUDING BIOMOLECULES, CELLS, TISSUES, OR**
26 **ORGANS.**

27 (2) **“QUALIFIED TECHNOLOGY” INCLUDES A TECHNOLOGY USED**
28 **FOR STEM CELL RESEARCH.**

29 [(i)] (j) “State–funded stem cell research” means stem cell research
30 conducted with State money and using:

1 (1) material obtained in accordance with § 10–438 of this subtitle; or

2 (2) adult stem cells.

3 **[(j)] (K)** “Stem cell” means a human cell that has the ability to:

4 (1) divide indefinitely;

5 (2) give rise to many other types of specialized cells; and

6 (3) give rise to new stem cells with identical potential.

7 **[(k)] (L)** “Valuable consideration” means financial gain or advantage in
8 connection with material obtained in accordance with § 10–438 of this subtitle.

9 10–430.

10 Nothing in this part may be construed to prohibit the creation of stem cell lines
11 to be used for therapeutic research purposes.

12 10–431.

13 (a) There is a Stem Cell **AND BIOTECHNOLOGIES** [Research]
14 **COMMERCIALIZATION** Commission.

15 (b) The Commission is an independent commission that functions in the
16 Corporation.

17 (c) The Commission consists of the following members:

18 (1) the Attorney General or the Attorney General’s designee;

19 (2) three patient advocates, one appointed by the Governor, one
20 appointed by the President of the Senate, and one appointed by the Speaker of the
21 House of Delegates;

22 (3) three individuals with experience in biotechnology, one appointed
23 by the Governor, one appointed by the President of the Senate, and one appointed by
24 the Speaker of the House of Delegates;

25 (4) two individuals who work [as scientists] **IN TECHNOLOGY**
26 **TRANSFER** for the University System of Maryland [and do not engage in stem cell
27 research], appointed by the University System of Maryland;

1 (5) two individuals who work [as scientists] **IN TECHNOLOGY**
2 **TRANSFER** for the Johns Hopkins University [and do not engage in stem cell
3 research], appointed by the Johns Hopkins University; **AND**

4 (6) [two bioethicists, one appointed by the University System of
5 Maryland and one appointed by the Johns Hopkins University; and

6 (7) two individuals with expertise in the field of biomedical ethics as it
7 relates to religion, appointed by the Governor] **TWO INDIVIDUALS WITH**
8 **EXPERIENCE IN INVESTING IN BIOTECHNOLOGY, APPOINTED BY THE**
9 **GOVERNOR.**

10 (d) (1) The term of an appointed member is 2 years.

11 (2) The terms of the appointed members are staggered as required by
12 the terms provided for members on October 1, 2008.

13 (3) At the end of a term, an appointed member continues to serve until
14 a successor is appointed and qualifies.

15 (4) An appointed member may not serve more than three consecutive
16 full terms.

17 (5) An appointed member who is appointed after a term has begun
18 serves only for the rest of the term and until a successor is appointed and qualifies.

19 (e) Each member of the Commission shall disclose to the State Commission
20 on Ethics whether the member is employed by or has a financial interest in an entity
21 that may apply to conduct State-funded stem cell research.

22 (f) The members of the Commission shall elect a chair from among the
23 appointed members of the Commission.

24 (g) A majority of the full authorized membership of the Commission is a
25 quorum.

26 (h) The Commission shall meet at least twice a year.

27 (i) A member of the Commission:

28 (1) may not receive compensation as a member of the Commission; but

29 (2) is entitled to reimbursement for expenses under the Standard
30 State Travel Regulations, as provided in the State budget.

1 (j) The Commission may employ a staff, including contractual staff, in
2 accordance with the State budget.

3 10-432.

4 (a) The Commission shall:

5 (1) adopt regulations that ensure that adult stem cell and stem cell
6 research financed by the Fund complies with State law;

7 (2) develop criteria, standards, and requirements for the initial review
8 of grant and loan applications by the Commission;

9 (3) review grant and loan applications to ensure that each application
10 is complete and satisfies the criteria, standards, and requirements developed by the
11 Commission, including approval by an institutional review board;

12 (4) establish procedures and guidelines to be used by the committee
13 for the review, evaluation, ranking, and rating of research proposals for State-funded
14 stem cell research **OR RESEARCH SUPPORTING A QUALIFIED TECHNOLOGY**;

15 [(5) ensure that the procedures and guidelines established under item
16 (4) of this subsection are based on the guidelines of the National Institutes of Health
17 Center for Scientific Review;]

18 [(6)] (5) establish criteria, standards, and requirements for
19 consideration of grant and loan applications based on the rankings and ratings of the
20 committee;

21 [(7)] (6) make recommendations consistent with the criteria,
22 standards, and requirements established by the Commission and based on the
23 rankings and ratings of the committee regarding the award of grants and loans from
24 the Fund;

25 [(8)] (7) establish standards for the oversight and use of awards;

26 [(9)] (8) conduct progress oversight reviews of recipients;

27 [(10)] (9) notify the Corporation regarding the submission by a
28 recipient, or failure of a recipient, to submit institutional review board approval for a
29 grant or loan awarded under this subtitle; and

30 [(11)] (10) develop guidelines on disclosure and recusal to be followed
31 by members of the Commission when considering grant and loan applications.

32 (b) The Commission may consult with experts in performing its duties.

1 10-434.

2 (a) There is a Maryland Stem Cell **AND BIOTECHNOLOGIES** [Research]
3 **COMMERCIALIZATION** Fund.

4 (b) [The purpose of the Fund is to promote State-funded stem cell research
5 and cures through grants and loans to public and private entities in the State] **A**
6 **PRIMARY PURPOSE OF THE FUND IS TO SUPPORT INNOVATIVE BIOTECHNOLOGY**
7 **RESEARCH AND DEVELOPMENT IN THE STATE THAT HAS THE POTENTIAL TO**
8 **CREATE SUSTAINABLE JOB GROWTH IN THE STATE, INCLUDING**
9 **MANUFACTURING JOBS.**

10 (c) The Corporation shall administer the Fund.

11 (d) (1) The Fund is a special, nonlapsing fund that is not subject to
12 reversion under § 7-302 of the State Finance and Procurement Article.

13 (2) The Treasurer shall hold the Fund separately, and the Comptroller
14 shall account for the Fund.

15 (e) The Fund consists of:

16 (1) appropriations as provided in the State budget; and

17 (2) any other money from any other source accepted for the benefit of
18 the Fund.

19 (f) Money in the Fund may only be used to:

20 (1) award grants and loans for State-funded stem cell research **OR**
21 **RESEARCH SUPPORTING A QUALIFIED TECHNOLOGY**, in accordance with the
22 recommendations of the Commission;

23 (2) award grants and loans for facilities, capital leases, and capital
24 equipment where State-funded stem cell research is conducted, in accordance with the
25 recommendations of the Commission; and

26 (3) pay the costs necessary to administer the Fund.

27 (g) (1) The Treasurer shall invest the money in the Fund in the same
28 manner as other State money may be invested.

29 (2) Any investment earnings shall be paid into the Fund.

1 (h) (1) The Governor may include in the State budget bill each fiscal year
2 an appropriation to the Fund.

3 (2) Expenditures from the Fund may only be made in accordance with
4 an appropriation approved by the General Assembly in the State budget or by an
5 approved budget amendment.

6 10-435.

7 (a) A grant or loan awarded under this part is contingent on the recipient:

8 (1) submitting to the Commission approval from an institutional
9 review board; and

10 (2) entering into a memorandum of understanding with the
11 Corporation that:

12 (i) establishes the scope of the State's ownership or other
13 financial interest in the commercialization and other benefits of the results, products,
14 inventions, and discoveries of State-funded stem cell research; and

15 (ii) to the extent consistent with federal and State law, reflects
16 the intellectual property policies of the institution.

17 (b) A recipient shall submit the approval required under subsection (a)(1) of
18 this section within 6 months after the award of the grant or loan.

19 (c) The Corporation may not disburse grant or loan money to a recipient
20 until:

21 (1) the recipient has obtained the approval required under subsection
22 (a)(1) of this section; and

23 (2) the recipient and the Corporation have entered into the
24 memorandum of understanding required under subsection (a)(2) of this section.

25 **(D) AT LEAST ONE-THIRD OF THE GRANTS OR LOANS AWARDED EACH**
26 **YEAR SHALL BE AWARDED TO FOR-PROFIT COMPANIES HEADQUARTERED IN**
27 **THE STATE.**

28 **(E) IN SELECTING RECIPIENTS FROM THE NONPROFIT SECTOR,**
29 **PRIORITY SHALL BE GIVEN TO APPLICANTS THAT HAVE CODEVELOPMENT**
30 **PARTNERSHIPS WITH STATE FOR-PROFIT COMPANIES, DETERMINED BY USING**
31 **THE MATCHING FUNDS FORMULA OF THE MARYLAND INDUSTRIAL**
32 **PARTNERSHIP PROGRAM.**

1 10-436.

2 (a) The Commission shall contract with an independent scientific peer
3 review committee composed of scientifically recognized experts in the field of stem cell
4 research **OR OTHER QUALIFIED TECHNOLOGIES.**

5 (b) The committee shall:

6 (1) review, evaluate, rank, and rate research proposals for
7 State-funded stem cell research:

8 (i) based on the procedures and guidelines established by the
9 Commission; **[and]**

10 (ii) in a manner that gives due consideration to the scientific,
11 medical, and ethical implications of the research; and

12 **(III) IN A MANNER THAT GIVES DUE CONSIDERATION TO THE**
13 **PROPRIETARY NATURE AND LONG-TERM COMMERCIAL POTENTIAL OF EACH**
14 **PROPOSAL; AND**

15 (2) make recommendations to the Commission, based on the rankings
16 and ratings awarded to research proposals by the committee, for the award and
17 disbursement of grants and loans under the Fund.

18 (c) A member of the committee:

19 (1) is not eligible to receive a grant or loan for State-funded stem cell
20 research from the Fund; **AND**

21 **[(2) may not reside in the State; and**

22 **(3)] (2)** shall be subject to conflict of interest standards that are at
23 least as stringent as the standards on conflict of interest adopted by the National
24 Institutes of Health.

25 **(D) AT LEAST ONE MEMBER OF THE COMMITTEE SHALL BE FROM THE**
26 **INDUSTRIAL SECTOR AND BE FAMILIAR WITH THE DEVELOPMENT AND**
27 **COMMERCIALIZATION OF BIOTECHNOLOGY PRODUCTS.**

28 10-437.

29 (a) A person who conducts State-funded stem cell research shall conduct the
30 research in a manner that considers the ethical and medical implications of the
31 research.

1 (b) A person who conducts State-funded stem cell research may not engage
2 in any research that intentionally and directly leads to human cloning.

3 10-438.

4 (a) A health care practitioner licensed under the Health Occupations Article
5 who treats individuals for infertility shall:

6 (1) provide individuals with information sufficient to enable them to
7 make an informed and voluntary choice regarding the disposition of any unused
8 material; and

9 (2) present to individuals the option of:

10 (i) storing or discarding any unused material;

11 (ii) donating any unused material for clinical purposes in the
12 treatment of infertility;

13 (iii) except as provided in subsection (b) of this section, donating
14 any unused material for research purposes; and

15 (iv) donating any unused material for adoption purposes.

16 (b) Any unused material donated for State-funded stem cell research may
17 not be an oocyte.

18 (c) An individual who donates any unused material for research purposes
19 under subsection (a)(2) of this section shall provide the health care practitioner with
20 written consent for the donation.

21 10-439.

22 (a) A person may not purchase, sell, transfer, or obtain any material donated
23 in accordance with § 10-438 of this subtitle for valuable consideration.

24 (b) A person may not give valuable consideration to another to encourage the
25 production of material donated in accordance with § 10-438 of this subtitle for the sole
26 purpose of medical research.

27 (c) A person who violates this section is guilty of a misdemeanor and on
28 conviction is subject to imprisonment not exceeding 3 years or a fine not exceeding
29 \$50,000 or both.

30 10-440.

31 (a) A person may not conduct or attempt to conduct human cloning.

1 (b) A person who violates this section is guilty of a felony and on conviction is
2 subject to imprisonment not exceeding 10 years or a fine not exceeding \$200,000 or
3 both.

4 10-441.

5 The Corporation, in consultation with the Commission, shall adopt regulations
6 to establish procedures for making the disbursement of a grant or loan contingent on
7 obtaining the approval of an institutional review board.

8 10-442.

9 (a) On or before January 1 of each year, the Corporation and the Commission
10 shall report to the Governor and, in accordance with § 2-1246 of the State
11 Government Article, the General Assembly on the progress of State-funded stem cell
12 research conducted in accordance with this part.

13 (b) The report shall identify:

14 (1) each recipient of money from the Fund;

15 (2) the amount of money awarded to each recipient; and

16 (3) a description of the type of stem cell research **OR RESEARCH**
17 **SUPPORTING A QUALIFIED TECHNOLOGY** performed by the recipient.

18 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
19 October 1, 2012.